K003559

APR 2 6 2001

510(K) Summary for the Siemens TCI

REVISED 4/16/01

1.	**Applicant's Name & Address:**	Siemens Hearing Instruments 10 Constitution Ave. PO Box 1397 Piscataway, NJ 08855
2.	**Contact Person, Telephone and e-mail Address:**	Dave Slavin 732-562-6658 dslavin@siemens-hearing.com
3.	**Device Trade of Proprietary Name:**	TCI (Tinnitus Control Instrument)
4.	**Device Common Name / Classification Name:**	**Tinnitus Masker**
	Product Code:	**KLW**
5.	**Establishment Registration Number:**	2217809
6.	**Address of Manufacturing Site:**	Siemens Hearing Instruments 10 Constitution Ave. PO Box 1397 Piscataway, NJ 08855
7.	**Classification of Device:**	Class II
8.	**Marketed Devices to which the claim of substantial equivalence is made:**	K974751 General Hearing Instruments Tranquil Tri-OE

9. Compliance with Section 514, Performance Standards: Not Applicable

10. Indications for Use:

The TCI is a behind-the-ear style electronic, air conduction broad-band noise generator intended to output noise of sufficient intensity and bandwidth to be used for tinnitus habituation therapy and is also suitable for tinnitus masking therapy. TCI is intended to be used by those individuals who experience tinnitus, and do not need or desire amplification. This device is fit by a qualified audiologist or other hearing healthcare professional familiar with the diagnosis of tinnitus and subsequent rehabilitation therapy.

The target population is primarily the adult population over 18 years of age. The target group for this product includes individuals reporting tinnitus who do not desire or need amplification. This product may also be used with children 5 years of age or older.

11. Description of Device:

TCI is a fully digital, low-level noise generator that was developed to be used along with appropriate counseling and/or tinnitus therapy. This product is programmable, with four selectable noises and variable output level. The output noise can be custom-tailored to the user's individual requirements. The unit is housed in a conventional behind-the-ear case.

12. Comparison Information to Predicate Device:

The TCI is substantially equivalent to the General Hearing Instruments Tranquil TRI-OE (K974751). The Tranquil is also a noiser for tinnitus, with no amplification characteristics. The Siemens TCI differs from the Tranquil, in that the TCI is a digital product and is fully programmable, which increases the flexibility of the device.

The following table compares the Siemens Hearing Instruments TCI device and General Hearing Instruments Tranquil Tri OE.

	Siemens Hearing Instrument TCI Device	General Hearing Instruments Tranquil Tri OE
Intended Use	Mask tinnitus as part of tinnitus management program	Mask tinnitus as part of tinnitus management program
Target Population	Adults and children (≥5 years) with tinnitus that are participating in a tinnitus management program	Adults with tinnitus that are participating in a tinnitus management program
Operation Circuit type Programmable Available noises Volume control	 Digital Yes Four Yes	 Analog No One Yes
Physical Description	Standard behind-the-ear instrument housing	Custom in-the-ear product
RSM Output Characteristics White noise Pink noise Speech noise High-tone noise	 71 dB SPL 69 dB SPL 69 dB SPL 76 dB SPL	 75 dB SPL
Volume control range	Programmable: OFF, 8 dB, 16 dB, 32 dB	40 dB

TCI Comparison with Predicate Device

13. Information required under Title 21, Section 874.3400, and not already provided above.

Risks:
There are no risks associated with this device because the output of the noiser does not exceed OSHA exposure limits (OSHA Regulations, Standard – 29 CFR 1910.95 Occupational Noise Exposure).

Hearing Healthcare Professional Diagnosis:
The sale and fitting of the Siemens TCI will only be conducted through a Hearing Healthcare Professional, such as an audiologist or otolaryngologist.

Benefits:
Relief of tinnitus symptoms may be provided by this device when utilized with appropriate counseling and/or tinnitus therapy.

Warnings for Safe Use:
As this device cannot deliver damaging sound intensity, no warning is required about sound output level. General use precautions are given in the User's Manual.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Dave Slavin, Director
Quality Assurance and Regulatory Affairs
Siemens Hearing Instruments
10 Constitution Avenue
P.O. Box 1397
Piscataway, NJ 08855

Re: K003559
Trade Name: TCI (Tinnitus Control Instrument)
Regulatory Class: II
Product Code: KLW
Regulation: 21 CFR 874.3400
Dated: February 20, 2001
Received: February 22, 2001

Dear Mr. Slavin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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James K. Kane

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K003559